

Mitchell E. Daniels, Jr. Governor

Gregory N. Larkin, M.D., F.A.A.F.P. State Health Commissioner

DATE:

September 22, 2010

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

A. Scott Gilliam, MBA, CP-FS

Director, Food Protection Program

SUBJECT:

Abbott Recall

#### **SUGGESTED**

**ACTION:** 

Unclassified Recall; Certain Similac-brand, powder infant formulas due to remote possibility of the presence of a small common beetle in the products; Recommend

notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. The recalled products were distributed in the U.S., Puerto Rico, Guam and some countries in the Caribbean. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-

233-7360.

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### **Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

# Abbott Voluntarily Recalls Certain Similac® Brand Powder Infant Formulas That Did Not Meet Its Quality Standards

## **Contact:**

Consumer Hotline (800) 986-8850

**FOR IMMEDIATE RELEASE** - Sept. 22, 2010 - ABBOTT PARK, Ill. - Abbott is initiating a proactive, voluntary recall of certain Similac-brand, powder infant formulas in the U.S., Puerto Rico, Guam and some countries in the Caribbean.

Abbott is recalling these products following an internal quality review, which detected the remote possibility of the presence of a small common beetle in the product produced in one production area in a single manufacturing facility. The United States Food and Drug Administration (FDA) has determined that while the formula containing these beetles poses no immediate health risk, there is a possibility that infants who consume formula containing the beetles or their larvae, could experience symptoms of gastrointestinal discomfort and refusal to eat as a result of small insect parts irritating the GI tract. If these symptoms persist for more than a few days, a physician should be consulted.

The recall of these powder infant formulas includes:

- Certain Similar powder product lines offered in plastic containers.
- Certain Similar powder product lines offered in sizes such as 8-ounce, 12.4-ounce and 12.9-ounce cans.

To immediately find out if the product in your possession is included in this recall, parents and caregivers should visit www.similac.com/recall<sup>9</sup>, and type in their lot number to determine if their product is affected, or call (800) 986-8850.

No Abbott liquid infant formulas are impacted. Products <u>not</u> involved in the recall include all Abbott Nutrition liquid ready-to-feed and concentrated infant formulas and all powder and liquid specialty formulas, such as Similac Expert Care<sup>TM</sup> Alimentum®, Elecare®, Similac Expert Care<sup>TM</sup> Neosure®, Similac® Human Milk Fortifier, and metabolic formulas for inherited disorders.

### About the Recall

- The company is implementing a plan to address this matter in the affected manufacturing facility, which is expected to be completed shortly. No other facilities or products are involved in this recall.
- Abbott has consulted with the U.S. FDA regarding this recall.

# **Information for Parents and Caregivers**

- Products with affected lot numbers should be returned to Abbott at no cost to the consumer.
- Parents and caregivers can go to www.similac.com/recall<sup>10</sup> or call Abbott's consumer hotline, (800) 986-8850, 24 hours a day, seven days a week.
- Both the website and the consumer hotline have specific details on how to complete the return process.

Holger Liepmann, executive vice president, Abbott Nutrition said:

"Abbott understands that parents expect to feed their children only the highest quality product. We are taking this action so that parents know that the infant formula products they provide unquestionably meet the highest quality standards for which they are known. We regret any inconvenience this situation poses to parents and consumers."

Photos: Product Labels<sup>11</sup>